

## **EPA Registration Jacket 90188-1**

# PROCESSING REQUEST

Reg #: 96188-1

Decision #: S00748

Description: AH#1 Added

## Material Available Electronically (see PPLS):

☐ Electronic Label/Letter Dated:

☐ Other:

## Material Sent (see jacket):

☐ Stamped Label/Letter Dated:

☐ Notification Dated:

☒ New CSF(s) Dated: 2/24/15

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Shanta Adee

Division: RO IHB

Phone: 347-0502

Date: 7/27/15



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

July 27, 2015

Jane Miller  
Agent  
ProNil, LLC  
c/o Biologic Consulting, Inc.  
115 Obtuse Hill Road  
Brookfield, CT 06804

Subject: PRIA CSF Amendment –Adding Alternate CSFs 1  
Product Name: Propanil Technical  
EPA Registration Number: 90188-1  
Application Date: February 24, 2015  
Decision Number: 500748

Dear Ms. Miller:

The Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 01/30/2014
- Alternate CSF 1 dated 02/24/2015

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, please contact Shanta Adeeb by phone at (703) 347-0502, or via email at [adeeb.shanta@epa.gov](mailto:adeeb.shanta@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "Reuben Baris".

Reuben Baris, Product Manager 25  
Herbicide Branch  
Registration Division (7505P)  
Office of Pesticide Programs



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

**FEE**

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS  
REGISTRATION DIVISION (7505P)

**DOCUMENT CONTAINS CONFIDENTIAL INFORMATION**

**DATE OUT:** July / 06 / 2015

**SUBJECT:** **PRODUCT CHEMISTRY REVIEW OF MP [ X ] EP [ ]**  
**DP BARCODE No.:** DP426460 **EPA Reg. No.:** 90188-1  
**PRODUCT NAME:** Propanil Technical  
**COMPANY:** Propanil, LLC  
**FOOD USE [ Yes ] INTEGRATED FORMULATION [ X ]**  
**PCC:** 028201 **Decision No.** 500748  
**ACTION CODE:** R351 **Pesticidal use:** Herbicide

**FROM:** Hari Mukhoty, MSc, PhD  
Product Chemistry Team  
Technical Review Branch / RD (7505P)

*Handwritten:* JMW - SBM 7/9/15

**TO:** Shanta Adeeb, RMR / Reuben Baris, RM 25  
Invertebrate & Vertebrate Branch 3 / RD (7505P)

**INTRODUCTION:**

The Registrant has submitted an amended CSF (Dated: 02/24/2015) as alternate formulation (Alt. # 1) to the aforesaid basic for registration under EPA Reg. No. 90188-1. The product chemistry data have been submitted under MRID: 495828-01 and -02.

The aforesaid alternate TGAI / MUP is manufactured by [REDACTED]

Chemical Analyses were performed by EPL Bio Analytical Services (EPL BAS), IL, USA.

Label text indicates that this proposed MUP is intended to be formulated into end-use products with food uses (Only Rice) & other uses approved by EPA.

CITAB has been requested to evaluate the product chemistry data required for the registration of the proposed MUP.

**SUMMARY OF FINDINGS:**

1. The proposed alternate TGAI/MUP contains the active ingredient: Propanil (98.5%).
2. The overall mean of the active ingredient from the five batch analysis is 98.717% [MRID: 495828-01, Page 15].

\*Manufacturing process information may be entitled to confidential treatment\*

**DP BARCODE No.:** 426460 **EPA Reg No.:** 90188-1 **PRODUCT NAME:** Propanil Technical

3. The proposed nominal concentration of the active ingredient in the MUP is 98.5%. The nominal concentration of the active ingredient (98.5%) matches with the label claim (98.5%). This is in compliance with PR Notice 91-2.

The certified limits of the active ingredients and impurities are standard. The limits are 3% around nominal for active and [REDACTED] for the impurities.

4. This CSF has been reviewed by I.I.A. Group and they have concluded that it contains active ingredient and impurities only.

5. The product chemistry data submitted for Group A corresponding to guidelines 830.1550 (product identity and composition), 830.1600 (description of materials used to produce the product), 830.1620 (description of production process), 830.1670 (discussion of formation of impurities), 830.1750 (certified limits) satisfy the product chemistry data requirements of 40 CFR §158.320, 158.325, 158.330, 158.340, and 158.350 respectively for the proposed formulation [MRIDs: 495828-01 & -02].

6. The active ingredient and [REDACTED] were quantified and characterized by GC / FID method. Karl Fischer Titration was used to quantify water content [MRID: 495828-01].

Validation data were provided for ingredients quantified.

Similar analytical techniques can also be applied for Enforcement Analytical Method.

7. Product chemistry Group A requirements are satisfied and acceptable [MRIDs: 495828-01]. Group B data are not required.

#### **CONCLUSIONS:**

1. CITAB has reviewed the CSF (dated: 02/24/2015) for the proposed alternate # 1 TGAI/MUP and has found it to be acceptable.

2. Product chemistry Group A data are satisfied and acceptable.

3. The proposed label was screened as it pertains to the product chemistry requirements. The final review of the proposed label and uses are the purview of the PM team.

DP BARCODE No.: 426460 EPA Reg No.: 90188-1 PRODUCT NAME: Propanil Technical

PRODUCT CHEMISTRY DATA (SERIES 830 Group A)

Group A	Data Required Fulfilled	MRID No.
830.1550. Chemical Identity (same as in Product CSF dated 02/24/2015)	A	495828-01 / 493099-01
830.1600. Beginning Materials	A	As basic 493099-01
830.1620. Production process	A	"
830.1650. Formulation process	NA	
830.1670. Discussion of Impurities	A	"
830.1700. Preliminary Analysis #	A	495828-01
830.1750. Certified Limits	A	CLs are standard. 3% for active & [REDACTED] for impurities. See Alt. # 1 CSF Dated: 02/24/2015
830.1800. Enforcement Analytical Method #	A	495828-01

A = Acceptable NA = Not Applicable G = data gap

# Analytical Methods: The active ingredient and [REDACTED] impurity were quantified and characterized by GC/FID method. Karl Fischer Titration was used to quantify water content [MRID: 495828-01].

\*Manufacturing process information may be entitled to confidential treatment\*

**DP BARCODE No.:** 426460 **EPA Reg No.:** 90188-1 **PRODUCT NAME:** Propanil Technical

Group B Data: Not required for alternate formulations (Alt. # 1).

Table 2: Physical and Chemical Properties of: Propanil Technical Alt. # 1				
GLN	Requirement	MRID	Status	Result or Deficiency
830.6302	Color			
830.6303	Physical state	493099-02	A	Solid
830.6304	Odor			
830.6313	Stability to normal and elevated temperatures, metals, and metal ions			
830.6314	Oxidation/reduction: chemical incompatibility			
830.6315	Flammability			
830.6316	Explosibility			
830.6317	Storage stability			
830.6319	Miscibility			
830.6320	Corrosion characteristics			
830.7000	pH	CSF dated: 02/24/2015	A	6.27
830.7050	UV/Visible absorption			
830.7100	Viscosity			
830.7200	Melting point			
830.7220	Boiling point			
830.7300	Density	CSF dated: 02/24/2015	A	0.728 g/cc
830.7370	Dissociation constants in water (DC)			
830.7550	Partition coefficient			
830.7840	Water solubility			
830.7950	Vapor pressure			
A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress ; U = Up-grade (additional information required); W = waivers				





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460  
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION  
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

**DP BARCODE No.:** D426460; **FILE SYMBOL No.:** 90188-1 (screen); **PRODUCT NAME:** Propanil Technical;  
**DECISION No.:** 500748; **PC Code(s):** 028201; **ACTION CODE:** R351; **FOOD Use:** Yes

**DATE OUT:** April 9, 2015

**SUBJECT:** Completeness check screening for technical product "Propanil Technical"

**FROM:** Shyam Mathur,  
Product Chemistry Team Leader  
CITAB / RD (7505P)

**TO:** Shanta Adeeb / Reuben Baris, RM 25  
Herbicide Branch / RD (7505P)

**Company Name:** Pronil LLC  
**Formulation Type:** Herbicide  
**Active Ingredient(s):** Propanil (98.5%)  
**MRID No(s).:** 49582801

**CONCLUSION:**

**Deficiencies:** No

(if there are deficiencies they are indicated below each heading as Note 1, Note 2 Etc)

**Group A:** All required data submitted & cited

**Group B:** All required data cited

**CSF:** Alternate CSF (dated 02-24-2015; produced [REDACTED]  
[REDACTED] submitted.

**Draft Product Label:** Submitted

Note to PM: If the deficiencies are found in the screen results, please inform the registrant and bring back to author of this report or to Joe the corrected deficiencies in response to 10 day letter, so that it can be attached to the original bean, if the data package is still in CITAB. New Bean is required in case the bean has been closed by CITAB. Thank you.

**\*Manufacturing process information may be entitled to confidential treatment\***



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
WASHINGTON, D.C. 20460

March 10, 2015

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

BIOLOGIC CONSULTING, INC.  
PRONIL, LLC  
115 OBTUSE HILL ROAD  
BROOKFIELD, CT 06804

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 02-MAR-15. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Receipt for Section 3

S: 965140

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: Amendment

Fee For Service: ☐ Yes ☒ No

Company: 90188 PRONIL, LLC

Billable: ☒ Yes ☐ No

V

Print Letter

Enter More Information

Tracking

Risk Manager: Registration Division, Risk Management Team 25

Product #: 90188-1

Product Name: PROPANIL TECHNICAL

Override#:

Me Too Section3: 71085-1

Me Too Product Name: RICECO PROPANIL TECHNICAL

Application Date: 24-Feb-2015

OPP Rec'd Date: 02-Mar-2015

Front End Date: 04-Mar-2015

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Adding an alternate manufacturing source

New Ingredient Request Date:

New Ingredient Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Receipt Content

CSF

View/Edit

February 24, 2015

**49582800**

Ms. Mindy Ondish  
Product Manager, PM Team 25  
Herbicide Branch  
Registration Division (7504P)  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
Ariel Rios Building  
1200 Pennsylvania Avenue, N.W.  
Washington, D.C. 20460

SUBJECT: Propanil Technical; EPA Reg. No. 90188-1. Application for an Amendment to Add an Alternate Manufacturing Source.

Dear Ms. Ondish:

On behalf of ProNil, LLC we are submitting an Application for Pesticide Amendment to add a currently unregistered manufacturing source for technical grade propanil to the above-mentioned product registration.

The following documents are enclosed to process this request:

Administrative Materials

- ✓ Application for Pesticide Amendment (EPA Form 8570-1).
- ✓ Certification With Respect to Citation of Data (EPA Form 8570-35).
- ✓ Data Matrix (EPA Form 8570-35)
- ✓ One (1) copy of the proposed alternate formulation Confidential Statement of Formula (EPA Form 8570-4).

Three (3) copies of the following data:

**49582801** Preliminary Analysis of Technical Propanil

- ✓ OPPT 830.1700
- ✓ OPPT 830.1750
- ✓ OPPT 830.1800

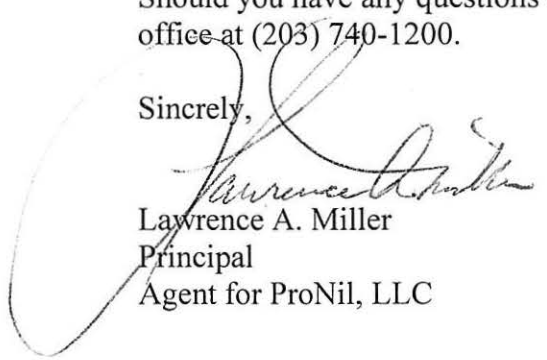
This application for a pesticide amendment will fall within the category on Table 5 – Registration Division: Amendments to Registration, R351, CR57. The PRIA Fee for this application is \$12,596.00 and a copy of the the email receipt is attached with this letter.

Ms. Ondish 2/24/15

Page 2

Should you have any questions or otherwise wish to reach me, please feel free to contact my office at (203) 740-1200.

Sincerely,



Lawrence A. Miller  
Principal  
Agent for ProNil, LLC



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

March 6, 2015

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OPP Decision Number: D-500748  
EPA File Symbol or Registration Number: 90188-1  
Product Name: PROPANIL TECHNICAL  
EPA Receipt Date: 02-Mar-2015  
EPA Company Number: 90188  
Company Name: PRONIL, LLC

JANE M. MILLER  
BIOLOGIC, INC.  
AGENT FOR PRONIL, LLC  
115 OBTUSE HILL ROAD  
BROOKFIELD, CT 06804-

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R351

AMENDMENT;UNREGISTERED SOURCE OF ACTIVE INGREDIENT;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 347-8961.

Sincerely,

A handwritten signature in black ink, appearing to be "m/jlc", is written over the word "Sincerely,".

Front End Processing Staff  
Information Technology & Resources Management Division

# Fee for Service

{964140t~

This package includes the following

- ☐ New Registration
- ☒ Amendment

- ☒ Studies?    ☐ Fee Waiver?
- ☐ volpay    % Reduction: \_\_\_\_

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr.

25

Receipt No.

S-

964140

EPA File Symbol/Reg. No.

90188-1

Pin-Punch Date:

3/2/2015

- ☐ This item is NOT subject to FFS action.

## Action Code:

Requested:

R351

Granted:

R351

Amount Due: \$ 12,556.18

## Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: 

Date: 3-6-15

Remarks:

# PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 3-2-15

Experts In-Processing Signature: B.B. Date 3-9-15 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date \_\_\_\_\_

EPA Reg. Number: <u>90188-1</u>		EPA Receipt Date: <u>3-2-15</u>					
Items for Review					Yes	No	N/A*
1	<b>Application Form</b> (EPA Form 8570-1) signed & complete including package type				X		
2	<b>Confidential Statement of Formula</b> all boxes completed, form signed, and dated (EPA Form 8570-4)				X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A) <i>no inerts to review</i>	yes	no				
3	<b>Certification with Respect to Citation of Data</b> (EPA Form 8570-34) completed and signed (N/A if 100% repack)				X		
	Certificate and data matrix consistent				X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no				
	If applicable, is there a letter of Authorization for exclusive use only.						
4	<b>Formulator's Exemption Statement</b> (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)						X
	<b>Data Matrix</b> (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)				X		
5	a) Selective Method (Fee category experts use)	X					
	b) Cite-All (Fee category experts use)						
	c) Applicant owns all data (Fee category experts use)						
6	<b>5 Copies of Label</b> (Electronic labels on CD are encouraged and guidance is available)						X
7	<b>Is the data package consistent with PR Notice 86-5</b>				X		
8	<b>Notice of Filing</b> included with petitions						X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

**Comments:**

\* Documentation: (PASS) / FAIL  
required forms are complete

\* Issues: (PASS) / FAIL  
no issues to review

\* PRN 11-3: (PASS) / FAIL  
MRZD: 493828

\* Overall Status: (PASS) / FAIL

JIL 3-19-15

February 24, 2015

Ms. Mindy Ondish  
Product Manager, PM Team 25  
Herbicide Branch  
Registration Division (7504P)  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
Ariel Rios Building  
1200 Pennsylvania Avenue, N.W.  
Washington, D.C. 20460

SUBJECT: Propanil Technical; EPA Reg. No. 90188-1. Application for an Amendment to Add an Alternate Manufacturing Source.

Dear Ms. Ondish:

On behalf of ProNil, LLC we are submitting an Application for Pesticide Amendment to add a currently unregistered manufacturing source for technical grade propanil to the above-mentioned product registration.

The following documents are enclosed to process this request:

Administrative Materials

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- ✓ Certification With Respect to Citation of Data (EPA Form 8570-35).
- ✓ Data Matrix (EPA Form 8570-35)
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Three (3) copies of the following data:

Preliminary Analysis of Technical Propanil

- ✓ OPPT 830.1700
- ✓ OPPT 830.1750
- ✓ OPPT 830.1800

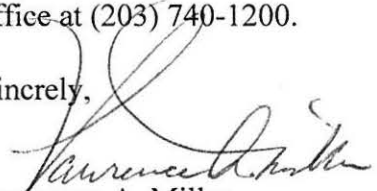
This application for a pesticide amendment will fall within the category on Table 5 – Registration Division: Amendments to Registration, R351, CR57. The PRIA Fee for this application is \$12,596.00 and a copy of the the email receipt is attached with this letter.

Ms. Ondish 2/24/15

Page 2

Should you have any questions or otherwise wish to reach me, please feel free to contact my office at (203) 740-1200.

Sincerely,



Lawrence A. Miller  
Principal  
Agent for ProNil, LLC



United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☒ Amendment  
☐ Other

OPP Identifier Number

**Application for Pesticide - Section I**

1. Company/Product Number 90188-1	2. EPA Product Manager M. Ondish	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Propanil Technical	PM# 25	
5. Name and Address of Applicant (Include ZIP Code) ProNil, LLC c/o Biologic, Inc. 115 Obtuse Hill Road Brookfield, CT 06804 <input type="checkbox"/> Check if this is a new address	6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

**Section - II**

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

This amendment is to add an unregistered source of the active ingredient to the formulation. This action will fall within the category as stated in Table 5 - Registration Division: Amendments to Registration as published in the Federal Register. This product is further defined under EPA No. R351; CR No. 57. The PRIA fee for this registration action is therefore \$12,596.

Jane M. Miller - Tel: 203-740-1200; Fax: 203-740-1220; Email: jmill@biologicconsulting.com

**Section - III**

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

**Section - IV**

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Jane M. Miller	Title Agent	Telephone No. (Include Area Code) (203) 740-1200	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped) 
2. Signature 	3. Title Agent		
4. Typed Name Jane M. Miller	5. Date February 24, 2015		



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number ProNil LLC/o Biologic Consulting, Inc. 115 Obtuse Hill Road Brookfield, CT 06804	EPA Registration Number/File Symbol 90188-1
Active Ingredient(s) and/or representative test compound(s) Propanil	Date February 24, 2015
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial food	Product Name Propanil Technical

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date Feb. 24, 2015	Typed or Printed Name and Title Jane M. Miller, Agent
---------------	-----------------------	--



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**1200 Pennsylvania Avenue, N.W.**  
**Washington, DC 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the form to this address.

**Data Matrix**

<b>Date:</b> February 26, 2015	<b>EPA Reg. No./File Symbol:</b> 90188-1	<b>Page 1 of 4</b>
<b>Applicant's/Registrant's Name and Address:</b> ProNil, LLC c/o Biologic Consulting, Inc. 115 Obtuse Hill Road Brookfield, CT 06804	<b>Product Name:</b> Propanil Technical	
<b>Ingredients: Active and Percent Propanil 98.5%</b>		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Notes
----------------------------	----------------------	-------------	-----------	--------	-------

**§ 158.310: Product Chemistry Data Requirements**

830.1550	Product identity and composition	49309901	ProNil, LLC	Own	
830.1600	Description of materials used to produce the product	49309901	ProNil, LLC	Own	
830.1620	Description of production process	49309901	ProNil, LLC	Own	
830.1650	Description of formulation process				1
830.1670	Discussion of formation of impurities	49309901	ProNil, LLC	Own	
830.1700	Preliminary analysis	49309902	ProNil, LLC	Own	
830.1750	Certified limits	49309902	ProNil, LLC	Own	
830.1800	Enforcement analytical method	49309902	ProNil, LLC	Own	
830.1900	Submittal of samples				2

**Physical and Chemical Properties**

830.6302	Color	49309902	ProNil, LLC	Own	
830.6303	Physical state	49309902	ProNil, LLC	Own	
830.6304	Odor	49309902	ProNil, LLC	Own	
830.6313	Stability (sunlight, temperatures, metals and ions)	49309902	ProNil, LLC	Own	
830.6314	Oxidation/reduction: chemical compatibility	49309902	ProNil, LLC	Own	
830.6315	Flammability				3
830.6316	Explosibility				4
830.6317	Storage stability of product				5
830.6319	Miscibility				6
830.6320	Corrosion characteristics				7
830.6321	Dielectric breakdown voltage				8
830.7000	pH	49309902	ProNil, LLC	Own	
830.7050	UV/Visible Spectrum	49309902	ProNil, LLC	Own	
830.7100	Viscosity				9

**Signature:**

*Jane M. Miller*

**Name and Title:**  
**Jane M. Miller**  
**Agent**

**Date:**

**02/24/2015**



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**1200 Pennsylvania Avenue, N.W.**  
**Washington, DC 20460**

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**Data Matrix**

<b>Date:</b> February 26, 2015	<b>EPA Reg. No./File Symbol:</b> 90188-1	<b>Page 2 of 4</b>
<b>Applicant's/Registrant's Name and Address:</b> ProNil, LLC c/o Biologic Consulting, Inc. 115 Obtuse Hill Road Brookfield, CT 06804	<b>Product Name:</b> Propanil Technical	
<b>Ingredients: Active and Percent Propanil 98.5%</b>		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Notes
830.7200	Melting point/melting range	49309902	ProNil, LLC	Own	
830.7220	Boiling point/boiling range	49309902	ProNil, LLC	Own	
830.7300	Density/relative density/bulk density	49309902	ProNil, LLC	Own	
830.7370	Dissociation constant	49309902	ProNil, LLC	Own	
830.7520	Particle size, fiber strength, diameter distribution				
830.7550 830.7560 830.7570	Partition coefficient (n-octanol/water)	49309902	ProNil, LLC	Own	
830.7840 830.7860	Water solubility	49309902	ProNil, LLC	Own	
830.7950	Vapor pressure				10
<b>§ 158.500: Toxicology Data Requirements</b>					
870.1100	Acute oral toxicity	Cite-All		PAY	
870.1200	Acute dermal toxicity	Cite-All		PAY	
870.1300	Acute inhalation toxicity	Cite-All		PAY	
870.2400	Primary eye irritation	Cite-All		PAY	
870.2500	Primary dermal irritation	Cite-All		PAY	
870.2600	Dermal sensitization	Cite-All		PAY	
Remaining data requirements including acute toxicity, ecological effects, environmental fate and all other generic data requirements required for agricultural uses, including task forces:		Cite-All		PAY	
The following companies have been sent Offer to Pay letters:			E.I. Dupont de Nemours	PAY	
			Wilmington, DE		
			Monsanto Company	PAY	
			Washington, DC		
			Drexel Chemical Company	PAY	
			Memphis, TN		

Signature:

**Name and Title:**  
**Jane M. Miller**  
**Agent**

Date:

02/24/2015



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<b>Applicant's/Registrant's Name and Address:</b> ProNil, LLC c/o Biologic Consulting, Inc. 115 Obtuse Hill Road Brookfield, CT 06804		<b>Product Name:</b> Propanil Technical
<b>Ingredients: Active and Percent Propanil</b> 98.5%		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Notes
			Propanil Risk Force	PAY	
			Washington, DC		
			Spray Drift Task Force	PAY	
			Washington, DC		
			United Phosphorus Inc.	PAY	
			King of Prussia, PA		
			RiceCo	PAY	
			Memphis, TN		
			Outdoor Residential TF	PAY	
			Washington, DC		
			Agricultural Reentry Task Force	PAY	
			Washington, DC		
			FIFRA Endangered Species TF	PAY	
			Washington, DC		
			Agricultural Handlers Exposure TF	PAY	
			Macon, MO		
			Propanil Task Force II	PAY	
			Washington, DC		
			Generic Endangered Species TF	PAY	
			Gig Harbor, WA		
			Willowood LLC	PAY	
			Gig Harbor, WA		
			Willowood Propanil LLC	PAY	
			Hockessin, DE		

Signature:

Name and Title:

Jane M. Miller  
Agent

Date:

02/24/2015



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**Data Matrix**

<b>Date:</b> February 26, 2015	<b>EPA Reg. No./File Symbol:</b> 90188-1	<b>Page</b> 4 of 4
<b>Applicant's/Registrant's Name and Address:</b> ProNil, LLC c/o Biologic Consulting, Inc. 115 Obtuse Hill Road Brookfield, CT 06804		<b>Product Name:</b> Propanil Technical
<b>Ingredients: Active and Percent Propanil 98.5%</b>		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Notes

**Notes**

1. N/A: Product is a TGA, not an EP	6. N/A: Product is a solid.
2. Samples will be submitted upon Agency request	7. In progress.
3. N/A: Product does not contain combustible materials.	8. N/A: Product is not for use in/on/around electrical equipment
4. N/A: Product is not potentially explosive.	9. N/A: Product is a solid.
5. In progress.	10. N/A Product is a solid at ambient temperatures and would therefore have negligible vapor pressure under normal storage conditions.

**Signature:**

*Jane M. Miller*

**Name and Title:**

Jane M. Miller  
Agent

**Date:**

02/24/2015

## Jane Miller

---

**From:** notification@pay.gov  
**Sent:** Thursday, February 19, 2015 3:57 PM  
**To:** jmill@biologicconsulting.com  
**Subject:** Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or [yanchulis.michael@epa.gov](mailto:yanchulis.michael@epa.gov).

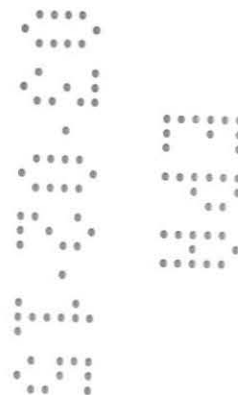
Application Name: PRIA Service Fees  
Pay.gov Tracking ID: 25JSR2SQ  
Agency Tracking ID: 74756020127  
Transaction Type: Sale  
Transaction Date: 02/19/2015 03:57:03 PM EST

Account Holder Name: John Steffell

Transaction Amount: \$12,596.00  
Billing Address: 17925 elm grove road  
Billing Address 2:  
City: platte city  
State/Province: MO  
Zip/Postal Code: 64079  
Country: USA  
Card Type: Visa  
Card Number: \*\*\*\*\*1861

Registration Number: 90188-1  
Company Name: ProNil, LLC  
Company Number: 90188  
Action Code: R351

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.



# PROCESSING REQUEST

Reg #: 90188-1

Decision #: 487371

Description: New Product

## Material Available Electronically (see PPLS):

☒ Electronic Label/Letter Dated: 12/17/14

☐ Other:

## Material Sent (see jacket):

☐ Stamped Label/Letter Dated:

☐ Notification Dated:

☒ New CSF(s) Dated: 1/30/14

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Emily Schmid

Division: RD

Phone: 347-0189

Date: 12/24/14



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs

Registration Division (7505P)

1200 Pennsylvania Ave., N.W.

Washington, D.C. 20460

EPA Reg. Number:

90188-1

Date of Issuance:

12/17/2014

NOTICE OF PESTICIDE:

☒ Registration

☐ Reregistration  
(under FIFRA, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product:

Propanil Technical

Name and Address of Registrant (include ZIP Code):

ProNil, LLC  
c/o Biologic Consulting, Inc.  
115 Obtuse Hill Road  
Brookfield, CT

**Note:** Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data.
2. The data requirements for storage stability and corrosion characteristics (Guidelines 830.6317 and 830.6320) are not satisfied. A one year study is required to satisfy these data requirements. You have 18 months from the date of registration to provide these data.

Continued on page 2

Signature of Approving Official:

Mindy Ondish, Acting Product Manager 25  
Herbicide Branch, Registration Division (7505P)

Date:

12/17/2014

3. Submit one copy of the revised final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6. Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records. Please also note that the record for this product currently contains the following CSFs:

- Basic CSF dated 1/30/2014

If you have any questions, please contact Emily Schmid at (703) 347-0189 or [schmid.emily@epa.gov](mailto:schmid.emily@epa.gov).

Enclosure

# Propanil Technical

For Manufacturing or Formulating Use Only

	By Weight
ACTIVE INGREDIENT: Propanil 3,4-dichloropropionanilide.....	98.5%
OTHER INGREDIENTS: .....	1.5%
TOTAL	100.0%

**KEEP OUT OF REACH OF CHILDREN**

## CAUTION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

### FIRST AID

- |                      |  |
|----------------------|--|
| <b>IF IN EYES:</b>   | <ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li><li>• Remove contact lens, if present after the first five minutes, and then continue rinsing.</li></ul>   |
| <b>IF SWALLOWED:</b> | <ul style="list-style-type: none"><li>• Call a poison control center or doctor for treatment advice.</li><li>• Have the person sip a glass of water if able to swallow.</li><li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li><li>• Do not give anything to an unconscious person.</li></ul> |
| <b>IF INHALED:</b>   | <ul style="list-style-type: none"><li>• Move person to fresh air.</li><li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.</li></ul>  |
| <b>IF ON SKIN:</b>   | <ul style="list-style-type: none"><li>• Call a poison control center or doctor for further treatment advice.</li><li>• Take off contaminated clothing.</li><li>• Rinse skin immediately with plenty of soap and water for 15-20 minutes.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>              |

### HOTLINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For information on this product, contact the National Pesticide Information Center at 1-800-858-7378. You may also contact the National Poison Control Center, 1-800-222-1222, day or night, for emergency medical treatment information.

**NET WEIGHT: XX Lbs. (Kgs.)**

Manufactured for:  
ProNil, LLC  
P.O. Box 4473  
St. Joseph, MO 64504

**ACCEPTED**

12/17/2014

Under the Federal Insecticide, Fungicide  
and Rodenticide Act as amended, for the  
pesticide registered under  
EPA Reg. No. 90188-1

EPA Reg. No. 90188- 1  
EPA Est. No.

## **PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

### **ENVIRONMENTAL HAZARDS**

This product is toxic to fish and aquatic invertebrates. Do not discharge effluent containing this pesticide into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. Do not contaminate water when disposing of equipment washwaters. For guidance, contact your State Water Board or Regional Office of the EPA.

### **DIRECTIONS FOR USE**

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Only for formulation into an herbicide for the following use(s): Rice.

This product may be used to formulate products for any additional use(s) not listed on the manufacturing use product (MP) label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s).

This product may be used for experimental purposes that are in compliance with U.S. EPA requirements.

Formulators using the product are responsible for obtaining EPA registration for their formulated products.

After March 1, 2012, the manufacturing use product may not be formulated into dry flowable end-use products unless they are packaged in closed systems or unless the Agency has changed the dry flowable mitigation based on submitted data.

### **STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage or disposal.

**PESTICIDE STORAGE:** Open dumping is prohibited. Do not store this product near fertilizers, seeds, insecticides, or fungicides. Do not store near heat or open flame. Containers should not be stacked more than 3 units high. Reclose all partially used containers by tying bag top shut. Damaged or leaking containers which contain product that cannot be used immediately should be transferred to suitable sound containers and properly marked. Any spilled material should be thoroughly swept up and transferred to the new container or disposed of as indicated under Pesticide Disposal.

**PESTICIDE DISPOSAL:** Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**CONTAINER HANDLING: Nonrefillable container:** Do not reuse or refill this container. Offer for recycling if available. Completely empty bag into formulation equipment. Then offer for recycling if available, or dispose of empty bag in a sanitary landfill or by incineration if allowed by state and local authorities.

**STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED:** Scoop or shovel solid material into a suitable container for recovery or disposal. Remove contaminated clothing promptly and wash exposed skin areas with soap and water. Wash clothing before reuse. Keep spill out of sewers and open bodies of water. Refer to PRECAUTIONARY STATEMENTS.

## **LIMITATION OF WARRANTY AND LIABILITY**

**NOTICE:** Read this Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded. ProNil, LLC warrants that this product conforms to the chemical description on the label thereof and is reasonably fit for the purpose stated in the directions under normal conditions. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, PRONIL, LLC MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY OR ANY OTHER EXPRESS OR IMPLIED WARRANTY. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, IN NO EVENT SHALL PRONIL, LLC OR SELLER BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT. BUYERS OR USERS BARGAINED-FOR EXPECTATION IS CROP PROTECTION. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER AND THE EXCLUSIVE LIABILITY OF PRONIL, LLC OR SELLER, FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY OR CONTRACT, NEGLIGENCE, TORT OR STRICT LIABILITY), WHETHER FROM FAILURE TO PERFORM OR INJURY TO CROPS OR OTHER PLANTS, AND RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT, OR AT THE ELECTION OF PRONIL, LLC OR SELLER, THE REPLACEMENT OF THE PRODUCT. To the extent consistent with applicable law that allows such requirement, buyers and all users shall promptly notify ProNil, LLC of any claims, whether based on contract, negligence, strict liability, other tort or otherwise, or be barred from any remedy. This Limitation of Warranty and Liability may not be amended by any oral or written agreement.

Resubmission

**Schmid, Emily**

---

**From:** Jane Miller <jmiller@biologicconsulting.com>  
**Sent:** Wednesday, December 17, 2014 8:46 AM  
**To:** Schmid, Emily  
**Subject:** RE: Propanil Technical (EPA File Symbol 90188-R)  
**Attachments:** 90188-1.20141217.Propanil Technical.revised Label.pdf

Hi Emily,

Here is the label.

Thank you,

*Jane M. Miller*

**BIOLOGIC CONSULTING, INC.**

115 Obtuse Hill Road

Brookfield, CT 06804

Tel: 203.740.1200

Fex: 203.740.1220

---

**From:** Schmid, Emily [mailto:Schmid.Emily@epa.gov]  
**Sent:** Tuesday, December 16, 2014 9:07 PM  
**To:** jmiller@biologicconsulting.com  
**Subject:** RE: Propanil Technical (EPA File Symbol 90188-R)

Hi Jane,

I have attached the pdf of Propanil Technical with comments.

I'm glad to hear you think I have been efficient but I hope that any actions I work on for you in the future won't be so close to the PRIA date. A few of these were reassigned to me during our reorganization. Anyway, you have made these actions much easier than they could have been.

Let me know if you have any questions.

Best regards,  
Emily

---

**From:** Jane Miller [mailto:jmiller@biologicconsulting.com]  
**Sent:** Monday, December 15, 2014 5:05 PM  
**To:** Schmid, Emily  
**Subject:** RE: Propanil Technical (EPA File Symbol 90188-R)

Here it is. I will not get sick of you. I am thrilled to get my work completed so efficiently.

Regards,

*Jane M. Miller*

**BIOLOGIC CONSULTING, INC.**

115 Obtuse Hill Road

Brookfield, CT 06804

Tel: 203.740.1200  
Fax: 203.740.1220

---

**From:** Schmid, Emily [<mailto:Schmid.Emily@epa.gov>]  
**Sent:** Monday, December 15, 2014 3:03 PM  
**To:** Jane M. Miller  
**Subject:** Propanil Technical (EPA File Symbol 90188-R)

Hi Jane,

Propanil Technical (EPA File Symbol 90188-R) is another one of your submissions that has been assigned to me. You must be getting really sick of me!

Could you email a pdf of the label to me?

Thank you,

Emily Schmid  
U.S. Environmental Protection Agency  
Registration Division  
Herbicide Branch



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND  
POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS  
REGISTRATION DIVISION (7505P)

16/DEC/2014

SIMILARITY MEMORANDUM

Subject: Name of Pesticide Product: Propanil Technical  
EPA Reg. No. /File Symbol: 90188-R  
DP Barcode: D424518  
Decision No: 487371  
Action Code: R333  
PC Code: 028201 (propanil)

From: Eugenia McAndrew, Biologist  
Chemistry, Inerts, Toxicology Assessment Branch  
Registration Division (7505P)

Handwritten signature of Eugenia McAndrew.

Handwritten signature of M. Hasdin.  
TOXICOLOGIST

To: Emily Schmid, Risk Management Team 25  
Herbicide Branch  
Registration Division (7505P)

Applicant: ProNil  
P.O. Box 4473  
St. Joseph, MO 64504

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Propanil	98.5

<u>Other Ingredients:</u>	<u>1.5</u>
Total:	100.0%

**ACTION REQUESTED:** Similarity determination for 90188-R, proposed product, and 71085-1, cited product.

**BACKGROUND:** Pronil has applied for registration of Propanil Technical, EPA File Symbol 90188-R, claiming to be substantially similar to Propanil Technical, EPA Reg. No. 71085-1. Both products are technical grade for manufacturing use only. The submission includes a basic CSF dated January 30, 2014, a label and data matrix. The source of active ingredient is unregistered.

The registrant is using the cite all method of data support to satisfy the acute toxicity data requirements. A search of the OPP electronic databases shows that the Product Reregistration Branch assigned an acute toxicity profile to 71085-1 in a 2007 memo (Lewis; D339729; EPA Reg. No. 71085-1; 09/MAY/2007).

#### **RECOMMENDATIONS:**

1. We compared the basic CSFs and labels of the proposed product, 90188-R, and the cited product, 71085-1, and determined that the two products are substantially similar.
2. The acute toxicity profile for the proposed product, Propanil Technical, EPA File Symbol 90188-R, is as follows:

acute oral toxicity	III	cited	EPA Reg. No. 71085-1
acute dermal toxicity	IV	cited	EPA Reg. No. 71085-1
acute inhalation toxicity	IV	cited	EPA Reg. No. 71085-1
primary eye irritation	III	cited	EPA Reg. No. 71085-1
primary skin irritation	IV	cited	EPA Reg. No. 71085-1
dermal sensitization	negative	cited	EPA Reg. No. 71085-1

3. The proposed basic CSF submitted for 90188-R must be reviewed and accepted by the product chemists in the Chemistry, Inerts, Toxicology Assessment Branch.

**LABELING:** Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System:

**PRODUCT ID #:** 090188-00001

**PRODUCT NAME:** Propanil Technical

#### **PRECAUTIONARY STATEMENTS**

**SIGNAL WORD:** CAUTION

#### **Hazards to Humans and Domestic Animals:**

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

**First Aid:**

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

May 9, 2007

*for profile of  
active product*

MEMORANDUM:

Subject: EPA Reg. No.: 71085-1/Riceco Propanil Technical  
DP Barcode: 339729  
Case No.: 0226

From: Marianne Lewis, Biologist [sign. M.Lewis 5/9/07]  
Product Reregistration Branch  
Special Review and Reregistration Division (7508C)

To: Moana Appleyard, CRM  
Product Reregistration Branch  
Special Review and Reregistration Division (7508C)

Applicant: RiceCo LLC  
5100 Poplar Avenue  
Suite 2428  
Memphis, TN

FORMULATION FROM EPA Reg. No. 71085-1 LABEL:

	<u>% by wt.</u>
<u>Active Ingredient(s):</u>	
Propanil .....	98.0%
<u>Inert Ingredient(s):</u> .....	2.0%
Total	100.0%

BACKGROUND: In the 8 month response to the Propanil RED, the registrant is citing acute toxicity studies to support the reregistration of their product, EPA Reg. No. 71085-1. The MRID's are as follows: 447515-02 (81-1), 446859-01 (81-2), 446859-02 (81-3), 447515-03 (81-4), 447515-04 (81-5), 447515-05 (81-6). The studies were conducted by Product Safety Labs. The test material used in each of the studies was EPA Reg. No. 71085-21 which is listed in Batch 1 of the RED along with the subject product. These studies were reviewed and found to be acceptable by TRB/RD on 10/8/02. After reviewing the studies listed above PRB concurs with TRB's findings.

RECOMMENDATIONS:

- The acute toxicity studies cited are acceptable to support the reregistration of EPA Reg. No. 71085-1.

The acute toxicity profile for EPA Reg. No. 71085-1 is currently:

Acute Oral	III	Acceptable
Acute Dermal	IV	Acceptable
Acute Inhalation	IV	Acceptable
Primary Eye	III	Acceptable
Primary Dermal	IV	Acceptable
Skin Sensitization	non sensitizer	Acceptable

NOTE: The acute toxicity requirements have been satisfied for the subject product.

**LABELING:**

**ID #:** 071085-00001

RICECO PROPANIL TECHNICAL

**SIGNAL WORD:**

**CAUTION**

**HAZARDS TO HUMANS AND DOMESTIC ANIMALS\*:**

Harmful if swallowed. Causes moderate eye irritation. Avoid contact with eyes or clothing. Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

\*The designation of Personal Protective Equipment (PPE) for manufacturing use products does not fall under the jurisdiction of EPA, therefore, PPE has not been specified for this product.

**FIRST AID:**

IF SWALLOWED: Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION  
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

**FEE**

DP Barcode No.: 418272      File Symbol No.: 90188-R      Decision No.: 487371  
PC Code: 028201      Action Code: R 333  
Food Use: No      Product Name: Propanil Technical

Date: December 15, 2014

SUBJECT: Product Chemistry Review of the Manufacturing Use Product, Propanil Technical

FROM: Bruce F. Kitchens, Chemist  
Chemistry, Inert and Toxicology Assessment Branch/RD (7505P)  
Registration Division (7505P)

*Bruce F. Kitchens*  
12/15/14

TO: RM #, Emily Schmid  
Herbicide Branch  
Registration Division (7505P)

*RM #*  
12/16/14

INTRODUCTION:

The registrant, Pronil LLC, is submitting an application for the registration of the new manufacturing use product, Propanil Technical. The active ingredient in this product is Propanil at a label nominal concentration of 98.5% a.i. This product is intended for use in the manufacture of herbicide end-use products. In addition, the registrant's cover letter dated states that the proposed product is substantially similar in composition to EPA Reg. No. 71085-1 RiceCo Propanil Technical. In support of this request, the registrant has submitted a basic Confidential Statement of Formula (CSF) dated 30 Jan 2014, a draft label, and product chemistry data contained in MRID#s 493099-01 and 493099-02. The Chemistry, Inerts and Toxicology Assessment Branch (CITAB) has been asked to review this submission.

SUMMARY OF FINDINGS:

CITAB has reviewed this submission and reports the following findings:

1. This product is produced from an integrated formulation system. This means that the product is the result of intended chemical reactions.
2. All impurities have been assayed and identified by the registrant. The registrant has not declared any impurities of toxicological concern in this product. All impurities have a nominal concentration and upper certified limits.
3. The nominal concentration of the active ingredient listed on the proposed CSF and the draft label are the same.
4. The draft label contains the appropriate storage and disposal statements.
5. The active ingredient's certified limits as proposed on the basic CSF are acceptable.

DP Barcode No.: 418272  
PC Code: 028201  
Food Use: No

File Symbol No.: 90188-R  
Action Code: R 333  
Product Name: Propanil Technical

Decision No.: 487371

**CONCLUSIONS:**

CITAB has reviewed this submission and concludes the following:

1. The basic formula CSF for the proposed manufacturing use product, Propanil Technical dated 30 Jan 2014 is acceptable.
2. This submission satisfies the data requirements as specified in 40 CFR 158.320, 158.325, 158.330, 158.340, 158.345, 158.350, and 158.355 with respect to product identity and composition, description of materials used to produce the product, description of formulation process, discussion of formation of impurities, certified limits, and enforcement analytical method.
3. This submission satisfies the data requirements as specified in 40 CFR 158.310 with respect to physical and chemical properties except for storage stability and corrosion characteristics. The registrant states that studies are in progress to satisfy the data requirements for the storage stability and corrosion characteristics.
4. This product has been determined to be substantially similar in composition to EPA Reg. No. 71085-1 Riceco Propanil Technical from a product chemistry standpoint only.

DP Barcode No.: D418272

PC Code: 028201

Food Use: No

File Symbol No.: 90188-R

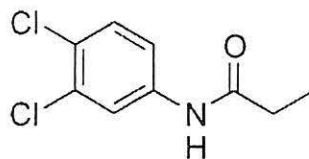
Action Code: R 333

Product Name: Propanil Technical

Decision No.: 487371

830.1550. Product Identity & Composition:

Common Name: Propanil  
Chemical Name: 3,4-dichloropropanilide  
CAS No.: 709-98-8  
PC Code No.: 028201  
Empirical formula:  $C_9H_9Cl_2NO$   
Molecular Weight: 218.1  
Structural formula:



**PROPANIL**

DP Barcode No.: D418272

File Symbol No.: 90188-R

Decision No.: 487371

PC Code: 028201

Action Code: R 333

Food Use: No

Product Name: Propanil Technical

\*Manufacturing process information may be entitled to confidential treatment\*

Table 1. Manufacturing and Impurity Data for Propanil Technical				
GLN	Requirement	MRID	Status	Details and /or Deficiency
830.1550	Product Identity and Composition	493099-01	A	The NC of AI (98.50%) is supported by 5 batch analysis & agrees with the label claim NC. [REDACTED] impurities ( $\geq 0.1\%$ ) are listed on the CSF
830.1600	Description of Materials Used to Produce the Product	493099-01	A	The product specification sheets (MSDS) for all the starting materials have been provided by the registrant
830.1620	Description of Production Process	493099-01	A	The active ingredient is produced in a batch process which involves [REDACTED] [REDACTED] The production process has been described in full detail. The reaction conditions, amounts of chemicals in each step, duration of time, and the yields in each step have been provided. The QA steps involved in each step have been described.
830.1670	Discussion of Formation of Impurities	493099-01	A	The registrant has provided the complete mechanisms of formation, quantification and identification of all the impurities present at the levels of $\geq 0.1\%$ . Total of [REDACTED] impurities have been listed on the CSF including [REDACTED]. No toxic impurity was reported during the synthesis.
830.1700	Preliminary Analysis	493099-01	A	The registrant has provided the analysis for ten batches of the active ingredient. The active ingredient and impurities were identified and quantified using gas chromatography with flame ionization detection. The methods were validated for accuracy, linearity, and precision. The active ingredient and impurities were identified by mass spectroscopy (MS). The LOQ and LOD for the active ingredient and each impurity were determined. The five batch analysis supported the CSF for basic formulation.
830.1750	Certified Limits	see basic csf 1/30/14	A	The proposed certified limits for the AI & for the impurities are based on the five batch analytical results.
830.1800	Enforcement Analytical Method	493099-01	A	The active ingredient and impurities were determined by gas chromatography using flame ionization detection (GC/FID). The method was validated for accuracy, precision and linearity.
A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress or need upgrade; U = Up-grade (additional information required)				

DP Barcode No.: D418272

File Symbol No.: 90188-R

Decision No.: 487371

PC Code: 028201

Action Code: R 333

Food Use: No

Product Name: Propanil Technical

## 830 Series Subgroup B (Physical-Chemical Properties)

Table 2: Physical and Chemical Properties of Propanil Technical						
GLN	Requirement	MRID	Status	Result or Deficiency		
830.6302	C o l o r	493099-02	A	Gray		
830.6303	Physical state	493099-02	A	Amorphous solid		
830.6304	Odor	493099-02	A	Naphthalene-like odor		
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	493099-02	A	The active ingredient stable when exposed to normal and elevated temperatures. The active ingredient was also stable when metals and metal ions.		
830.6314	Oxidation/reduction: chemical incompatibility	493099-02	A	Compatible with oxidizing & reducing agents, water, ammonium phosphate, iron powder, and potassium permanganate.		
830.6315	Flammability		NA	Product is an amorphous sold.		
830.6316	Explodability		NA	Product does not contain explosive components		
830.6317	Storage stability		I	Study in progress		
830.6320	Corrosion characteristics		I	Study in progress		
830.7000	pH	493099-02	A	6.27		
830.7050	UV/Visible absorption	493099-02	A	pH neutral acidic basic	$\Lambda_{\text{MAX}}$ 210 nm 210nm 249nm	$\epsilon$ 20478 21044 21772
830.7100	Viscosity		NA	Active ingredient is an amorphous solid.		
830.7200	Melting point	493099-02	A	92.9°C		
830.7220	Boiling point		NA	Active ingredient is an amorphous solid.		
830.7300	Density	493099-02	A	0.643 g/ml (pour)    0.728 g/ml (tap)		
830.7370	Dissociation constants in water	493099-02	A	pKa = 6.28 pI = 7.62		
830.7550	Partition coefficient	493099-02	A	Log P = 1.094		
830.7840	Water solubility:	493099-02	A	Water - 0.132 g/ml @ 23°C Methanol - 663.3 g/ml @ 23°C Hexane – 0.427 g/ml @ 23°C n-Octanol – 381.728 g/ml @ 23°C		
830.7950	Vapor pressure		NA	Product is an amorphous solid.		

Y = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress or need upgrade; U = Up-grade (additional information required)

DP Barcode No.: D418272

PC Code: 028201

Food Use: No

File Symbol No.: 90188-R

Action Code: R 333

Product Name: Propanil Technical

Decision No.: 487371

CONFIDENTIAL APPENDIX

**\*Manufacturing process information may be entitled to confidential treatment\***



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460  
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION  
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

**DP BARCODE No.:** D418272; **FILE SYMBOL No.:** 90188-R (screen); **PRODUCT NAME:** Propanil Technical  
; **DECISION No.:** 487371; **PC Code(s):** 028201; **ACTION CODE:** R333; **FOOD Use:** Yes

**DATE OUT:** March 25, 2014

**SUBJECT:** Completeness check screening for Technical product "Propanil Technical"

**FROM:** Shyam Mathur,  
Product Chemistry Team Leader  
Technical Review Branch/RD (7505P)

**TO:** Emily Schmid / Kable Davis, RM 25  
Herbicide Branch / RD (7505P)

**Company Name:** ProNil LLC  
**Formulation Type:** Herbicide  
**Active Ingredient(s):** Propanil ((98.5%))  
**MRID No(s):** 493099-01 & 493099-02

**CONCLUSION:**

**Group A:** Data submitted

**Group B:** Data submitted

**CSF:** Basic CSF (01-30-2014) submitted

**BIOLOGIC** INC.  
*agribusiness professionals*

January 30, 2014

Mr. Kable Bo Davis  
 Product Manager, PM Team 25  
 Herbicide Branch; Registration Division (7505P)  
 Office of Pesticide Programs  
 U.S. Environmental Protection Agency  
 Arial Rios Building  
 1200 Pennsylvania Avenue, N.W.  
 Washington, D.C. 20460

SUBJECT: Registration Application for "Propanil Technical"; EPA Reg. No. 90188-(to be assigned). Submitted on behalf of ProNil, LLC.

Dear Mr. Davis:

With this letter, please find the following enclosed items submitted on behalf of ProNil, LLC in support of its registration application for "Propanil Technical":

**Volume One – Administrative Materials**

- ✓ Application for Pesticide Registration; (EPA Form 8570-1)
- ✓ Data Matrix; (EPA Form 8570-35)
- ✓ EPA Confidential Statement of Formula; (EPA Form 8570-4)
- ✓ Certification with Respect to Citation of Data; (EPA Form 8570-34)
- ✓ Five (5) copies of draft labeling

**Volume Two – Manufacturing Process**

**49309901**

Product Identity and Composition of Propanil TGAI: Selected Studies to Fulfill OPPTS Guideline Series 830 in Accordance with 40 CFR Parts 158.155, 158.160, 158.162 and 158.167; Description of Materials to Produce the Product; Description of Production Process; Discussion of Formation of Impurities; and Certified Limits. OPPTS Guidelines 830.1550, 830.1600, 830.1620, 830.1670 and 830.1750. Project I.D. No. TOC-PRP-830.

**Volume Three – Preliminary Analysis and Part B Product Properties**

**49309902**

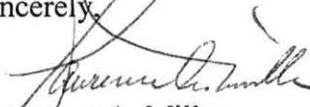
Determination of Physical and Chemical Characteristics and Preliminary Analysis of Technical Propanil. OPPTS Guidelines 830.1700, 830.1750, 830.1800, 830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.7000, 830.7050, 830.7200, 830.7300, 830.7370, 830.7550 and 830.7840. Project I.D. No. 533G406

Please be advised that this application is supported by the cite-all option in accordance with FIFRA 3(c)(1)(D) and offer to pay letters have been submitted to all companies listed under propanil on the September 25, 2013 Data Submitters List. Furthermore, the subject product is substantially similar in composition and labeling to "RiceCo Propanil Technical"; EPA Reg. No. 71085-1.

This registration action falls within the PRIA category as stated in Table 4 – Registration Division: New Products. This action is further defined under EPA No. R333; CR No. 52 as a "New Product" "MUP" "Unregistered Source of Active Ingredient". The PRIA fee for this registration action is, therefore, \$18,893.00 and the decision time frame is ten months. A copy of the receipt indicating this PRIA fee has been paid is included.

Should you have any questions or otherwise wish to reach me, please feel free to contact my office at (203) 740-1200.

Sincerely,



Lawrence A. Miller  
Principal  
Regulatory Agent for ProNil, LLC



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number ProNil, LLC c/o Biologic Consulting, Inc. 115 Obtuse Hill Road Brookfield, CT 06804	EPA Registration Number/File Symbol 90188-X
Active Ingredient(s) and/or representative test compound(s) Propanil	Date January 30, 2014
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Food	Product Name Propanil Technical

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT** (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study, and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

**I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.**

Signature 	Date Jan. 30, 2014	Typed or Printed Name and Title Jane M. Miller, Agent
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**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
WASHINGTON, D.C. 20460

February 11, 2014

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

JANE M. MILLER  
PRONIL, LLC  
115 OBTUSE HILL ROAD  
BROOKFIELD, CT 06804

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 03-FEB-14. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

# Receipt for Section 3

S: 947063

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Print Letter

Application Type: New Registration

Fee For Service: ☒ Yes ☐ No

Enter More Information

Billable: ☒ Yes ☐ No

Tracking

Company: 90188 PRONIL, LLC



Risk Manager: Registration Division, Risk Management Team 25

Product #: 90188-R Product Name: PROPANIL TECHNICAL

Override#:

Me Too

Me Too

Section3: 71085-1

Product Name: RICECO PROPANIL TECHNICAL

Application Date: 30-Jan-2014



OPP Rec'd Date: 03-Feb-2014



Front End Date: 03-Feb-2014



Risk Manager Send Date:



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Receipt Content

Study

CSF

View/Edit

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Application for registration of new MUP product

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:



United States  
Environmental Protection Agency  
Washington, DC 20460

☒  
☐  
☐

Registration  
Amendment  
Other

OPP Identifier Number

### Application for Pesticide - Section I

1. Company/Product Number 90188-X	2. EPA Product Manager K. Davis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Propanil Technical	PM# 25	
5. Name and Address of Applicant (Include ZIP Code) ProNil, LLC c/o Biologic Consulting, Inc. 115 Obtuse Hill Road Brookfield, CT 06804 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. 71085-1 Product Name RiceCo Propanil Technical	

### Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

This is an application for a new pesticide MUP product. This action will fall within the category on Table 4 - Registration Division: New Products, EPA No. R333; CR No. 52. The PRIA fee for this application is \$18,893.

Contact: Jane Miller at email: jmill@biologicconsulting.com

### Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	2. Type of Container <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input checked="" type="checkbox"/> Other (Specify) Poly bulk bags
* Certification must be submitted		If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 500 kg. (1102.3 lbs.)	5. Location of Label Directions <input checked="" type="checkbox"/> on label	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph Paper glued Stenciled <input type="checkbox"/> Other			


### Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name Jane M. Miller	Title Agent	Telephone No. (Include Area Code) 203-740-1200	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 	3. Title Agent		
4. Typed Name Jane M. Miller	5. Date January 30, 2014		

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

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**DATA MATRIX**

Date January 30, 2014			EPA Reg. No./File Symbol 90188-X		Page 1 of 5
Applicant's/Registrant's Name & Address			Product:		
ProNil, LLC c/o Biologic, Inc. 115 Obtuse Hill Road Brookfield, CT 06804			Propanil Technical		
Ingredient Propanil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830-1550	Product Identity and Composition		PRONIL, LLC	Own	
830.1600	Description of Materials Used to Produce the Product		PRONIL, LLC	Own	
830.1620	Description of Production Process		PRONIL, LLC	Own	
830-X650	Description of Formulation Process				1
830.1670	Discussion of Formation of Impurities		PRONIL, LLC	Own	
830.1700	Preliminary Analysis		PRONIL, LLC	Own	
830.1750	Certified Limits		PRONIL, LLC	Own	
830.1800	Enforcement Analytical Method		PRONIL, LLC	Own	
830.1900	Submittal of Samples				2
830.6302	Color		PRONIL, LLC	Own	
830.6303	Physical State		PRONIL, LLC	Own	
830.6304	Odor		PRONIL, LLC	Own	
830.6313	Stability to normal & elevated temp., metal, metal ion		PRONIL, LLC	Own	
830.6314	Oxidation/Reduction		PRONIL, LLC	Own	
830.6315	Flammability / Flame Extension				3
830.6316	Explosibility				4
830.6317	Storage Stability				5
Signature 			Name and Title		Date
			Jane M. Miller, Agent		01/30/2014

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.


**DATA MATRIX**

Date January 30, 2014			EPA Reg. No./File Symbol 90188-X		Page 2 of 5
Applicant's/Registrant's Name & Address			Product		
ProNil, LLC c/o Biologic, Inc. 115 Obtuse Hill Road Brookfield, CT 06804			Propanil Technical		
Ingredient Propanil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6319	Miscibility				6
830.6320	Corrosion Characteristics				7
830.6321	Dielectric Breakdown Voltage				8
830.7000	pH		PRONIL, LLC	Own	
830.7050	UV/Visible Spectrum		PRONIL, LLC	Own	
830.7100	Viscosity				9
830.7200	Melting Point/ Melting Range		PRONIL, LLC	Own	
830.7300	Density		PRONIL, LLC	Own	
830.7370	Dissociation Constant		PRONIL, LLC	Own	
830.7570	Octanol/Water Partition Coefficient		PRONIL, LLC	Own	
830.7840	Water Solubility		PRONIL, LLC	Own	
830.7950	Vapor Pressure				10
870.1100	Acute Oral Toxicity	CITE-ALL		PAY	
870.1200	Acute Dermal Toxicity	CITE-ALL		PAY	
870.1300	Acute Inhalation Toxicity	CITE-ALL		PAY	
870.2400	Acute Eye Irritation	CITE-ALL		PAY	
870.2500	Acute Dermal Irritation	CITE-ALL		PAY	
Signature			Name and Title		Date
			Jane M. Miller, Agent		01/30/2014

**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**401 M Street, S.W.**  
**WASHINGTON, D.C. 20460**

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**DATA MATRIX**

Date January 30, 2014		EPA Reg. No./File Symbol 90188-X		Page 3 of 5	
Applicant's/Registrant's Name & Address		Product:			
ProNil, LLC c/o Biologic, Inc. 115 Obtuse Hill Road Brookfield, CT 06804		Propanil Technical			
Ingredient Propanil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2600	Skin Sensitization			PAY	
Remaining data requirements including Acute Toxicity, Ecological Effects, Environmental Fate, and all other generic data requirements required for Agricultural uses, including task forces.		CITE-ALL		PAY	
The following companies have been sent Offer to Pay letters:			E.I. DuPont De Nemours	Pay	
			Wilmington, DE		
			Monsanto Company	Pay	
			Washington, DC		
			Drexel Chemical Company	Pay	
			Memphis, TN		
			Propanil Task Force	Pay	
			Washington, DC		
			Spray Drift Task Force	Pay	
			Washington, DC		
			United Phosphorus Inc.	Pay	
			King of Prussia, PA		
			RiceCo	Pay	
			Memphis, TN		
Signature			Name and Title		Date
			Jane M. Miller, Agent		01/30/2014

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**WASHINGTON, D.C. 20460**

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**DATA MATRIX**

Date January 30, 2014			EPA Reg. No./File Symbol 90188-X		Page 4 of 5
Applicant's/Registrant's Name & Address ProNil, LLC c/o Biologic, Inc. 115 Obtuse Hill Road Brookfield, CT 06804			Product <b>Propanil Technical</b>		
Ingredient Propanil					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
	CITE-ALL		Outdoor Residential Exposure TF	PAY	
			Washington, DC		
			Agricultural Reentry Task Force	PAY	
			Washington, DC		
			FIFRA Endangered Species TF	PAY	
			Washington, DC		
			Agricultural Handler Exposure TF	PAY	
			Macon, MO		
			Propanil Task Force II	PAY	
			Washington, DC		
			Generic Endangered Species TF	PAY	
			Gig Harbor, WA		
			Willowood, LLC	PAY	
			Gig Harbor, WA		
			Willowood Propanil, LLC	PAY	
			Hockessin, DE		
Signature 			Name and Title Jane M. Miller, Agent		Date 01/30/2014

### **DATA MATRIX FOOTNOTES**

1. **Description of Formulation Process:** Not applicable because the product is a TGA/MP.
2. **Submittal of Samples:** Not required at this time.
3. **Flammability / Flame Extension:** Not applicable. Product does not contain combustible liquids.
4. **Explodability:** Not applicable. Product is not potentially explosive.
5. **Storage Stability:** In progress.
6. **Miscibility:** Not applicable. Product is not intended for dilution with petroleum solvents.
7. **Corrosion Characteristics:** In progress.
8. **Dielectric Breakdown Voltage:** Not applicable. Product is not intended for use around electrical equipment.
9. **Viscosity:** Not required because product is a solid.
10. **Vapor Pressure:** Not required since Propanil is a solid at ambient temperatures and would therefore have negligible vapor pressure under normal storage conditions.

# Fee for Service

{947063\*~

This package includes the following

☒ New Registration

☐ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: \_\_\_\_

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr.

25

Receipt No.

S-

947063

EPA File Symbol/Reg. No.

90188-R

Pin-Punch Date:

2/3/2014

☐ This item is NOT subject to FFS action.

## Action Code:

Requested:

R333

Granted:

R333

Amount Due: \$ 18,853.

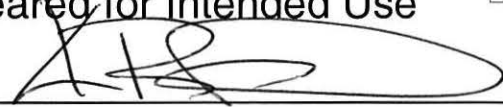
## Parent/Child Decisions:

☒ Inert Cleared for Intended Use



Uncleared Inert in Product

Reviewer:



Date: 2-4-14

Remarks:

# PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 2-3-14

Experts In-Processing Signature: B.B. Date 2-4-14 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date \_\_\_\_\_

EPA Reg. Number: <u>90188-R</u>		EPA Receipt Date: <u>2-3-14</u>				
Items for Review				Yes	No	N/A*
1	<b>Application Form</b> (EPA Form 8570-1) signed & complete including package type			X		
2	<b>Confidential Statement of Formula</b> all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
	<u>** No inerts to review</u>					
3	<b>Certification with Respect to Citation of Data</b> (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	<b>Formulator's Exemption Statement</b> (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
	<b>Data Matrix</b> (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)	X				
	c) Applicant owns all data (Fee category experts use)					
6	<b>5 Copies of Label</b> (Electronic labels on CD are encouraged and guidance is available)			X		
7	<b>Is the data package consistent with PR Notice 86-5</b>			X		
8	<b>Notice of Filing</b> included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

**Comments:**

\* Technical + impurities only, no inerts to review

\* Submitted studies PASSED PEN 11-3 review

\* Jacket PASSED

MRID: 493099

\* N/A – Not Applicable

#### Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at [inertsbranch@epa.gov](mailto:inertsbranch@epa.gov) and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

### **Unapproved Inerts Identified on CSFs**

#### **All applications except conventional new products and PIPs**

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

#### **Conventional New Product Applications**

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

### PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

**21-Day Screen Completed by**  
**Contractor**

**21-Day Expires on** 2-24-14

**Jacket #** 90188-R

**MRID#** 493099

**Content Screen:** Recommend to Pass/Fail

**11-3 Review:** Pass/Fail/NA

**Overall Status:** Recommend to Pass/Fail

**Transfer This Jacket to:**

STEPHEN SCHAIBLE

From: [paygovadmin@mail.doc.twai.gov](mailto:paygovadmin@mail.doc.twai.gov) [mailto:[paygovadmin@mail.doc.twai.gov](mailto:paygovadmin@mail.doc.twai.gov)]  
Sent: Friday, January 31, 2014 10:23 AM  
To: [john.steffel@tfholdingsone.com](mailto:john.steffel@tfholdingsone.com)  
Subject: Pay.gov Payment Confirmation: PRIA Service Fees

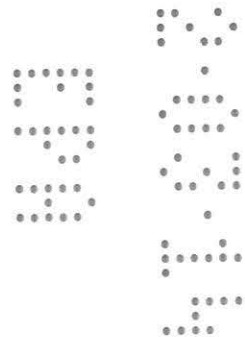
Your payment has been submitted to Pay.gov and the details are below. If you have any questions or you wish to cancel this payment, please contact Pay.gov Customer Service by phone at (800) 624-1373 or by email at [pay.gov.clev@clev.frb.org](mailto:pay.gov.clev@clev.frb.org).

Application Name: PRIA Service Fees  
Pay.gov Tracking ID: 25E6CLLP  
Agency Tracking ID: 74564654779  
Transaction Type: Sale  
Transaction Date: Jan 31, 2014 11:22:43 AM

Account Holder Name: john steffell  
Transaction Amount: \$18,893.00  
Billing Address: 17925 elm grove road  
City: platte city  
State/Province: MO  
Zip/Postal Code: 64079  
Country: USA  
Card Type: Visa  
Card Number: \*\*\*\*\*1861

Decision Number:  
Registration Number:  
Company Name: ProNil LLC  
Company Number: 90188  
Action Code: R333

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

February 4, 2014

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OPP Decision Number: D-487371  
EPA File Symbol or Registration Number: 90188-R  
Product Name: PROPANIL TECHNICAL  
EPA Receipt Date: 03-Feb-2014  
EPA Company Number: 90188  
Company Name: PRONIL, LLC

JANE M. MILLER  
PRONIL, LLC  
115 OBTUSE HILL ROAD  
BROOKFIELD, CT 06804-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R333

NEW PRODUCT;MUP OR END USE PRODUCT WITH UNREGISTERED SOURCE OF THE ACTIVE INGREDIENT;REQUIRES SCIENCE DATA REVIEW;NEW PHYSICAL FORM;CITE-ALL OR SELECTIVE DATA CITATION WHERE APPLICANT OWNS ALL REQUIRED DATA;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

*Peresa Downs*  
Front End Processing Staff

Information Technology & Resources Management Division

